

# MISSOURI BOARD OF PHARMACY

## ANNUAL REPORT

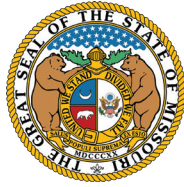


FY 2017

Eric R. Greitens, Governor  
State of Missouri

Chlora Lindley-Myers, Director  
Department of Insurance, Financial Institutions  
and Professional Registration

Kathleen (Katie) Steele Danner, Director  
Division of Professional Registration



Eric R. Greitens  
Governor  
State of Missouri

Kathleen (Katie) Steele Danner, Division Director  
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance,  
Financial Institutions and  
Professional Registration  
Chlora Lindley-Myers, Director

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To The Honorable Governor Eric Greitens:

In compliance with § 338.140.3, RSMO, the Missouri Board of Pharmacy is pleased to submit its Annual Report which contains the proceedings of the Board for the fiscal year ending June 30, 2017 ("FY 17"). The Board's mission is to protect the public in the regulation of pharmacy practice. The Board of Pharmacy is pleased to report another successful year.

Respectfully yours,  
MISSOURI BOARD OF PHARMACY  
By:

A handwritten signature in black ink, appearing to read "K A Grinston", written over a horizontal line.

Kimberly Grinston  
Executive Director



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Department of Insurance, Financial Institutions and  
Professional Registration

Division of Professional Registration

Missouri Board of Pharmacy

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**FY 2017**

**Board Members**

Christian Tadrus, PharmD., President

Douglas Lang, R.Ph., Vice-President

Barbara A. Bilek, PharmD., Member

Christina Lindsay, PharmD., Member

Pamela Marshall, RPh, Member

Anita K. Parran, Public Member

Vacant Positions (1)

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Kimberly A. Grinston, J.D., Executive Director

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# Executive Summary

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This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2016 to June 30, 2017 (FY17). The Board is pleased to announce another successful regulatory year as reflected below:

## Board Operations

- The Board held a total of 29 meetings, including, nine (9) regular session meetings, thirteen (13) conference call meetings, seven (7) email ballot meetings and two (2) Board sterile compounding subcommittee meetings/conference calls. The Board also hosted an additional 13 Working Group and Advisory Committee meetings.
- The Board received/responded to approximately 4,481 telephone calls. Call volume decreased for the second consecutive fiscal year while the availability of online services and online compliance resources continued to increase.

## Financial Overview

- The Board's total appropriation and authorized transfers for FY17 was \$2,647,054. Of the amount appropriated, the Board expended \$2,139,133.82.
- To ensure compliance with § 338.070, pharmacy technician renewal fees were decreased from \$35 to \$10 and pharmacist renewal fees decreased from \$ 200 to \$50. The Board subsequently experienced a 26% anticipated decrease in FY17 revenue to \$1,350,876.03. Board expenditures remained consistent with a slight 1.77% decrease.

## Licensing Summary

- Total licensees/registrants increased from 36,189 licensees/registrants in FY16 to 36,910 licensees/registrants in FY17, representing a moderate 1.99% increase.
- The number of licensed pharmacists decreased by 1.1%, representing the first pharmacist licensure decrease in more than 15 fiscal years. Though minor, the decrease is likely attributable to 36.7% fewer inactive pharmacists in FY17.
- Total registered pharmacy technicians remained consistent with a slight 3.4% increase to 19,912 technicians.
- Total licensed pharmacies remained consistent. Total licensed drug distributors and drug distributor registrants increased by 4.5% to 1,541 licensees/registrants which is consistent with historical licensing data after a drug distributor renewal year.

## Complaint Handling

- The Board received/opened 858 complaints in FY 17, representing a 19% increase primarily attributable to Missouri Department of Revenue tax suspension cases.
- Of the 858 complaints received/opened, 561 complaints were practice-related (65.3%) while 297 complaints were non-practice related Missouri Department of Revenue tax suspension cases (approx. 34.6%).

## Complaint Dispositions

- The Board closed/issued final dispositions on approximately 859 complaints, including, 298 Department of Revenue tax suspension complaints and 561 non-tax related complaints. Tax suspensions increased by 71%; Non-tax related complaint dispositions increased by 12%.

# Executive Summary

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## Disciplinary Actions

- The Board issued discipline in approximately 446 cases, representing a 43.8% increase in disciplinary actions taken. Of the 446 disciplinary actions taken, 148 disciplinary actions were practice related (33%) while 298 cases involved non-practice related Department of Revenue tax suspensions (67%). Practice related disciplinary actions increased by 8.8%.

## Inspections

- Board inspectors conducted a total of 1,260 inspections of pharmacies and drug distributors. 247 investigations were completed in FY 17, representing a 17% increase.
- Violations were observed or a Compliance Notice was issued in approximately 70% of inspections conducted, a decrease of 5%. Significantly, the number of inspections resolved with no violations noted increased by 22%.

## Compounded Drug Testing

- In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. 72.5% of products tested in FY17 were satisfactory while 27.5% were unsatisfactory.

## Rulemaking

- The Board promulgated the following rules in FY17:
  - 20 CSR 2220-2.095 (Collection of Medication for Destruction)
  - 20 CSR 2220-2.200 (Sterile Pharmaceuticals)
- Additionally, the following rule amendment was approved by the Board in FY17 but pending final Department approval for filing:
  - 20 CSR 2220-2.650 (Standards of Operation for a Class J: Shared Services Pharmacy)

## Board Initiatives

- The Board's strategic planning meeting was held on July 19, 2016. The Board voted to pursue six (6) legislative proposals related to pharmacy practice.
- The Board approved a 2020 Rule Review initiative aimed at reviewing all Board regulations before 2020.
- In addition to the Board's compliance webinars, the Board hosted two pharmacy diversion conferences in St. Louis and Kansas City to educate licensees on ways to detect and prevent pharmacy robbery and drug diversion.

# About the Board

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## Mission Statement

The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
- Licenses only qualified and competent professionals, and;
- Ensures compliance with professional standards and federal and state pharmacy law.

## ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Insurance, Financial Institutions and Professional Registration.

## MEMBERSHIP

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

## FUNCTIONS

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies and drug distributors;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/registrant;
- Inspection of pharmacies and drug distributors; and
- Approval of preceptors and intern training facilities.

# Board Operations



The Board held nine (9) regular session meetings, thirteen (13) conference call meetings and seven (7) email ballot meetings during FY17. In addition to Board meetings, the Board established a sterile compounding Board subcommittee which held three (3) meetings. The following Board Advisory Committee/Working Group meetings were also held during FY16:

- Hospital Advisory Committee (10 meetings)
- Pharmacy Technician Working Group (5 meetings)
- Long-Term Care Working Group (1 meeting)

## Staff

The following staff were employed by the Board during FY17:

### Staff

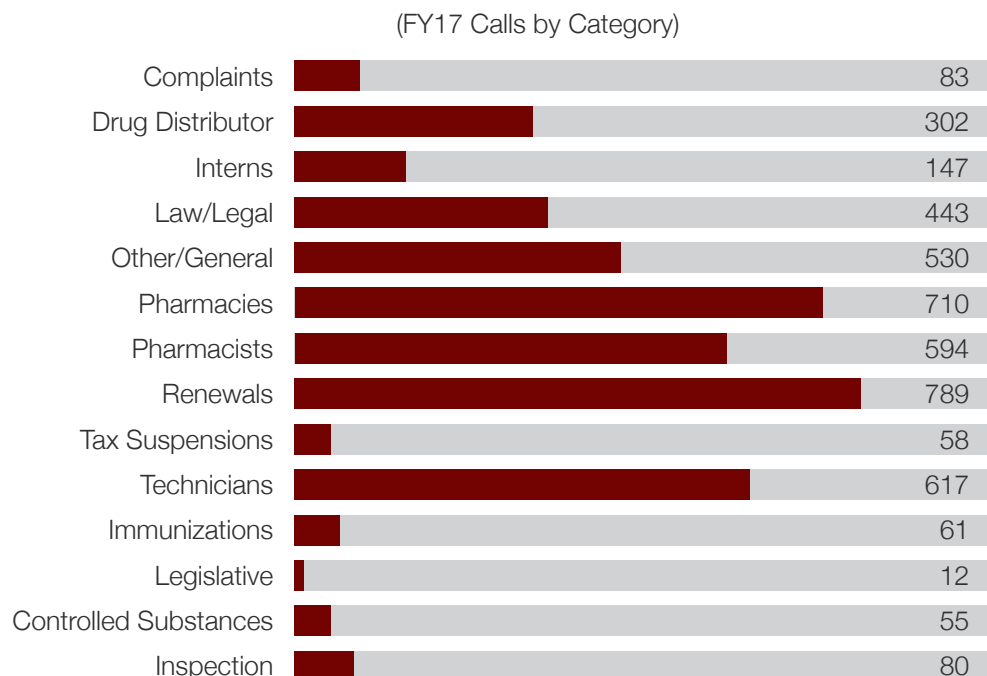
- Kimberly Grinston, J.D., Executive Director
- Jennifer Luebbert, Administrative Coordinator
- Laura Henke, Pharmacy/Drug Distributor Coordinator
- Christa Nilges, Senior Office Support Assistant
- Shelda Sternberg, Compliance Coordinator
- Tiffani Stumpf, Pharmacy Technician Coordinator
- Regina Walker, Pharmacist Coordinator

### Inspectors

- **Tom Glenski, R.Ph., Chief Inspector**
- Bennie Dean, R.Ph.
- Katie DeBold, PharmD.
- Joe Dino, R.Ph.
- Andrea “Andi” Miller, PharmD.
- Lisa Thompson, R.Ph.
- Daniel Vandersand, R.Ph.
- Elaina Wolzak, R.Ph.
- Barbara Wood, R.Ph.

## Office Activities

The Board received/responded to 4,481 telephone calls during FY17 representing a 19% decrease in call volume. While call volume decreased for the second consecutive fiscal year, the availability of online services and online compliance resources continued to increase. Major call topic areas are identified below:



\* Pharmacist category includes licensing, continuing education and audit related questions.





## Education/Training

As part of its ongoing efforts to promote compliance, the Board hosted the following compliance webinars in FY17 (participants were awarded free continuing education credit) :

- 2016: Sterile Compounding Garbing and Cleaning
- 2016: An Update on Sterile Compounding Regulations
- 2016: Legislative Update
- 2016: Sterile Compounding: Aseptic Technique Skill Assessment and Media Fills
- 2017: A Review of the New Drug Take-Back Regulation

The Board also hosted the following live programs:

- 2017 Missouri Pharmacy Diversion Conference (St. Louis- July 16, 2016)
- 2017 Missouri Pharmacy Diversion Conference (Kansas City- May 5, 2017)

## Gold Certificates

The following individuals received Gold Certificates during 2017 representing fifty (50) years of active service as a Missouri licensed pharmacist:

- |                      |                            |
|----------------------|----------------------------|
| • Grace A. Albano    | • Richard J. Kohout        |
| • Samuel J. Aleman   | • Raya J. Morris           |
| • Douglas J. Biggers | • Edward A. Nelson         |
| • Jay T. Bird        | • Robert D. Norman         |
| • Robert L. Bossler  | • Roger L. Prock           |
| • William R. Buntin  | • Cecil W. Propst          |
| • James E. Drake     | • Richard C. Purdue        |
| • Wayne C. Elgin     | • Wayne W. Reed            |
| • James P. Erdman    | • John R. Robinson         |
| • Thomas J. Faust    | • Herschel A. Ryales       |
| • John W. Foxworth   | • Thomas M. Schwarztrauber |
| • James P. Hess      | • Gary D. Shillito         |
| • John L. Keller     | • Theresa J. Stuart        |
| • Barry Kidder       | • Vernon L. Vespa          |

# Financial Summary



## Financial Overview

The Missouri Board of Pharmacy's appropriation for fiscal year ending June 30, 2017, was as follows:

Personal Service	\$ 1,089,799
Expense and Equipment	\$ 668,418
Criminal History Fund	\$ 5,000
Transfers*	\$ 883,837
	<hr/>
	\$ 2,647,054

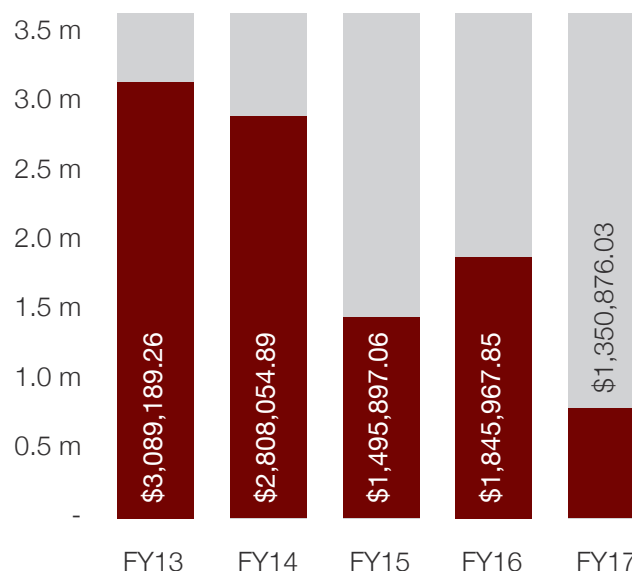
Of the amount appropriated, the Board expended \$ 2,139,133.82 in FY 17 as follows:

Personal Service	\$ 1,038,349.99 (48.54%)
Expense and Equipment	\$ 371,042.39 (17.34%)
Transfers*	\$ 729,741.44 (34.11%)

*\*Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.*

## Revenue Received:

The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that revenue produced does not substantially exceed the cost and expense of administering Chapter 338. In compliance with § 338.070, the Board lowered renewal fees in FY 17 for pharmacy technicians from \$35 to \$10 and for pharmacists from \$200 to \$50. The Board subsequently experienced a 26% anticipated decrease in FY17 revenue as reflected below:

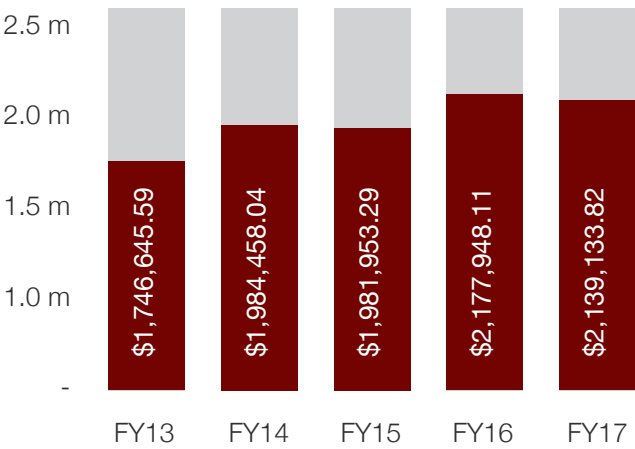


The Board will continue to monitor revenue trends to ensure compliance with § 338.070, RSMo.



## Board Expenditures:

Board expenditures remained consistent with a minor 1.7% decrease as reflected below:





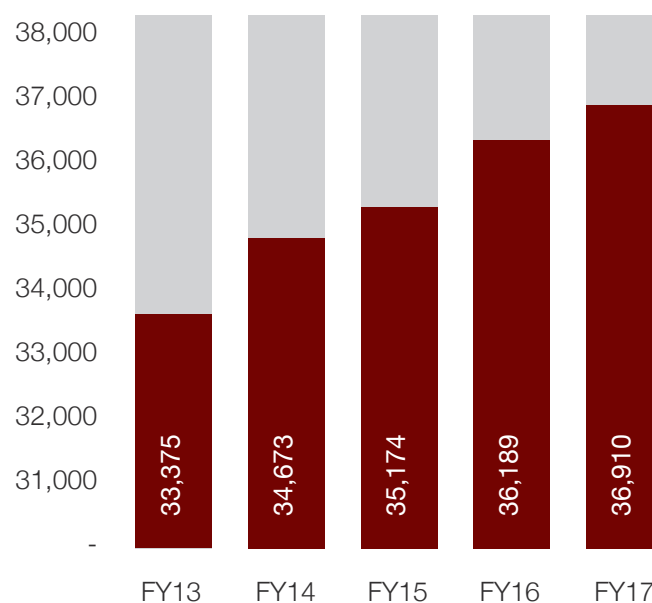
## Licensing Summary

Pursuant to Chapter 338, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies and drug distributors.

- The Board's total licensee/registrant count increased a slight 1.99% from 36,189 licensees/registrants in FY16 to 36,910 licensees/registrants in FY17. The reported increase is consistent with Board licensing history.
- The Board's licensing totals at the close of FY17 are provided by classification below:

LICENSING TOTALS	
Drug Distributors (licensed & temporary)	1,439
Drug Distributor Manufacturer Registrants	102
Intern Pharmacists	1,950
Pharmacists (active and inactive)	10,770
Pharmacists (temporary)	9
Pharmacies (instate, non-resident and temporary)	2,728
Pharmacy Technicians	19,912
<b>TOTAL</b>	<b>36,910</b>

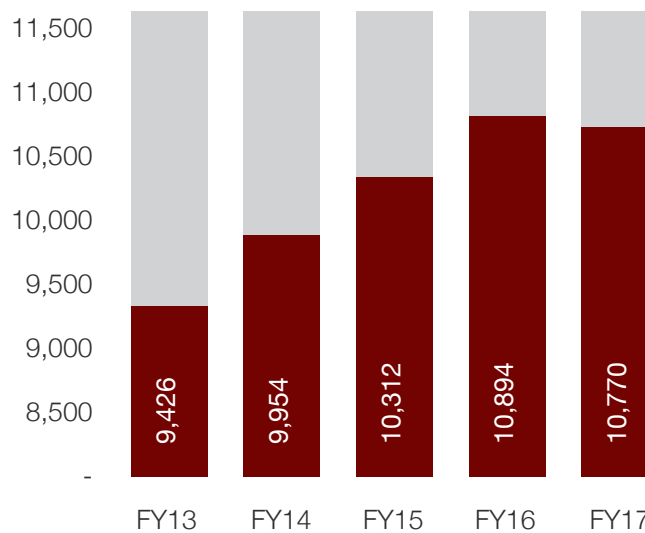
Total Licensees/Registrants by Fiscal Year





## Pharmacists:

Total licensed pharmacists decreased 1.1% to 10,770 pharmacists as reflected below. While the number of active pharmacists increased by 272 pharmacists in FY17, the number of inactive pharmacists decreased by 36.7% resulting in the first pharmacist license decline in more than 15 fiscal years.



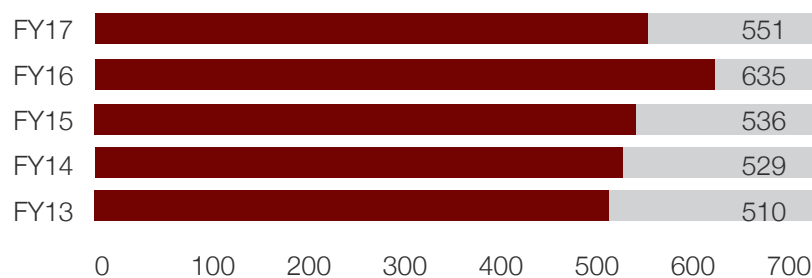
The total number of active vs. inactive Missouri pharmacists both resident and non-resident are reflected below:

Active Licensees	10,432
Male	4,696
Female	5,726
Inactive Licensees	338
<b>TOTAL LICENSED PHARMACISTS</b>	<b>10,770</b>

*\*\*Inactive pharmacists are not authorized to practice in Missouri but remain licensed.*

## Number of New Pharmacist Licenses Issued

The number of newly licensed pharmacists decreased by 13% as follows:

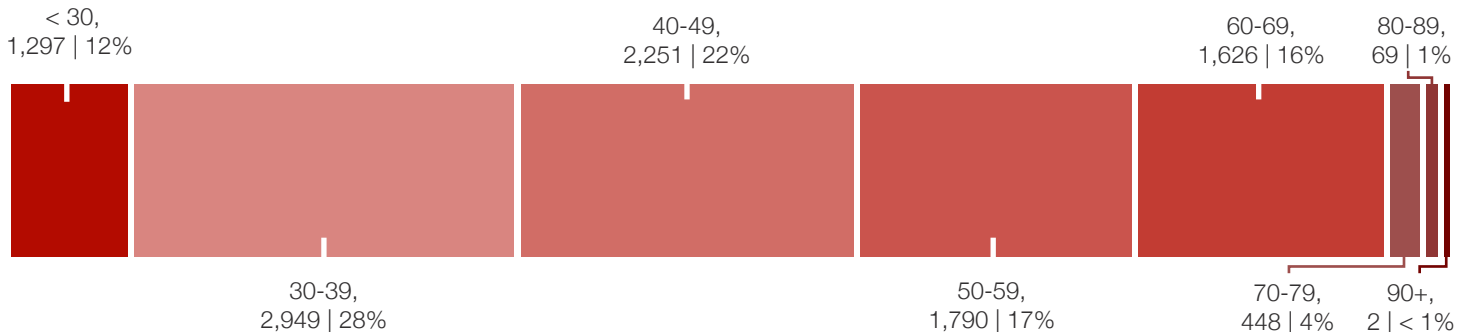




## Active Pharmacists By Age Group (Resident and Non-Resident) [#,%]

No significant changes occurred in the number of active pharmacists categorized by age. Forty percent (40%) of licensed Missouri pharmacists are age 39 and under with the remaining sixty percent (60%) at age 40 or above.

(Pharmacist Distribution by Age)



## Pharmacists Residing in Missouri

No significant changes occurred in actively licensed resident vs. non-resident pharmacists. Approximately 62.5% of pharmacists licensed by the Board reported a Missouri address as reflected below:

Resident Pharmacists	6,521
Non-Resident Pharmacists	3,911
<b>Total Missouri Resident Pharmacists</b>	<b>10,432</b>

## Administration & Immunizations:

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer vaccines pursuant to a protocol with a Missouri licensed physician, upon filing a Notification of Intent with the Board. At the end of FY 17:

- 2,613 pharmacists were authorized to administer medication by prescription.
- 2,885 pharmacists were authorized to administer immunizations by protocol.

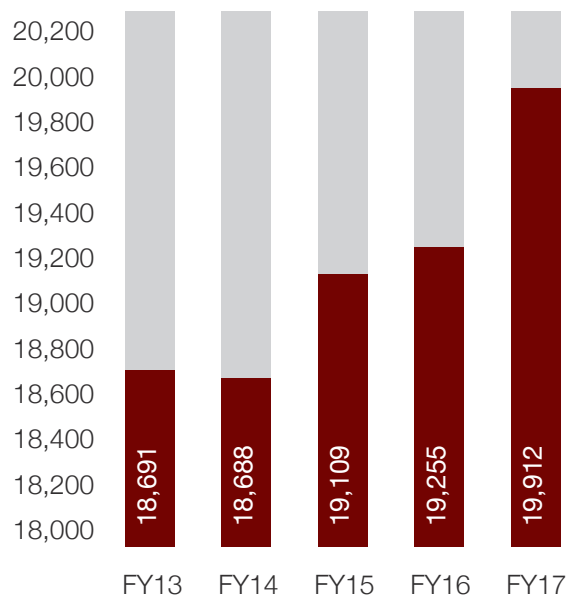
## Medication Therapy Services:

Section 338.010, RSMo, authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MTS certificate) which allows pharmacists to provide medication therapy services. A total of 2,650 pharmacists held a MTS certificate at the end of FY17 representing an 8.5% increase from FY16.



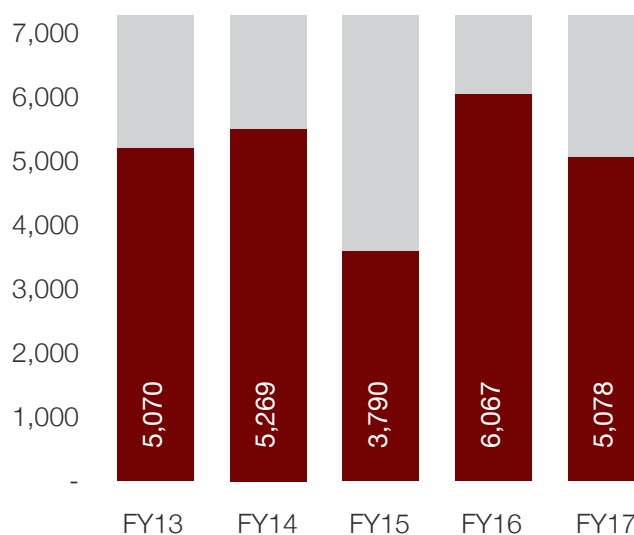
## Pharmacy Technicians:

The number of registered pharmacy technicians remained consistent with a slight 3.4% increase as reflected below:



## New Pharmacy Technician Registrations Issued

The percentage of newly registered technicians decreased by 16.3% in FY17. However, FY16 saw an atypical increase in newly issued registrations because of a delay in FY15 application processing due to vacancies in licensing staff. Although a decrease is noted, the number of FY17 newly registered technicians is consistent with Board historical licensing data prior to FY15 & FY16.



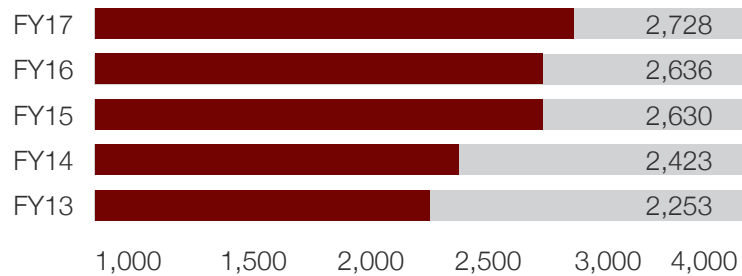


## Pharmacy Summary:

Total licensed pharmacies increased to 2,728 pharmacies, representing a minor 3.49% increase.

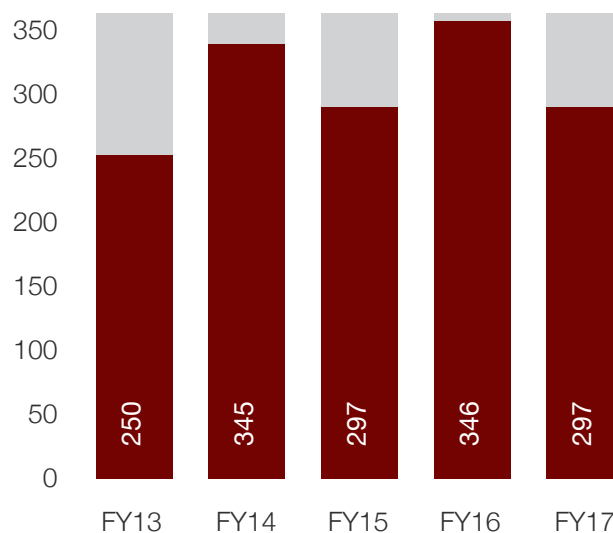
PHARMACY PERMIT TOTALS	
Instate Pharmacies	1,542
Non-Resident Pharmacies	1,177
Temporary Pharmacies	9
<b>TOTAL</b>	<b>2,728</b>

## Pharmacy Permitholders By Fiscal Year



## New Pharmacy Permits Issued

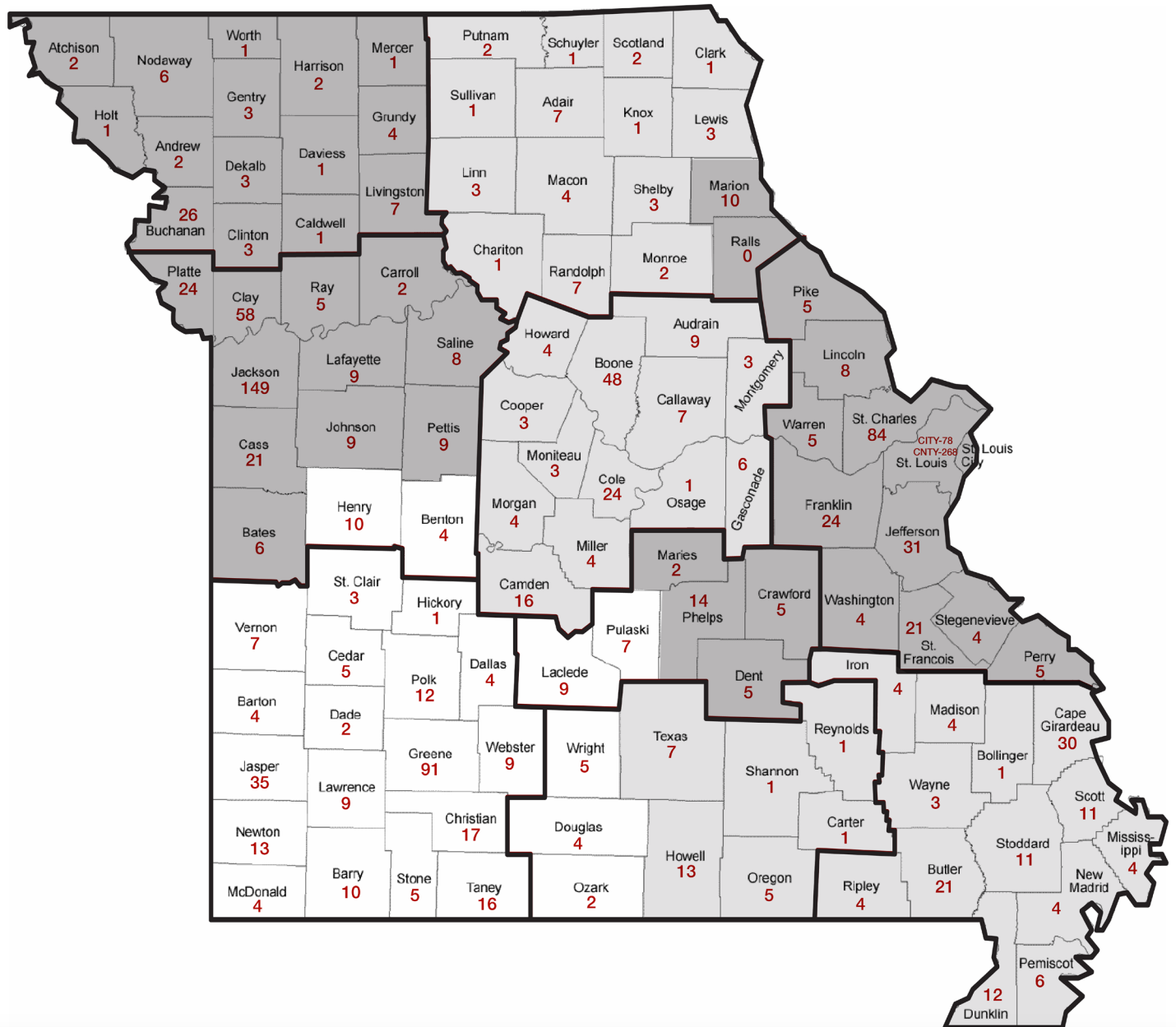
The Board experienced an approximate 14.45% decrease in new pharmacy permits as reflected below. However, the decrease is consistent with Board licensing history during a pharmacy non-renewal fiscal year.







## Missouri Pharmacies by County



### Statistics to Note:

- Number of counties with 0 pharmacies: 1 (Ralls County)
- Number of counties with < 10 pharmacies: 87
- Number of counties with 100+ pharmacies: 2 (St. Louis & Jackson County)

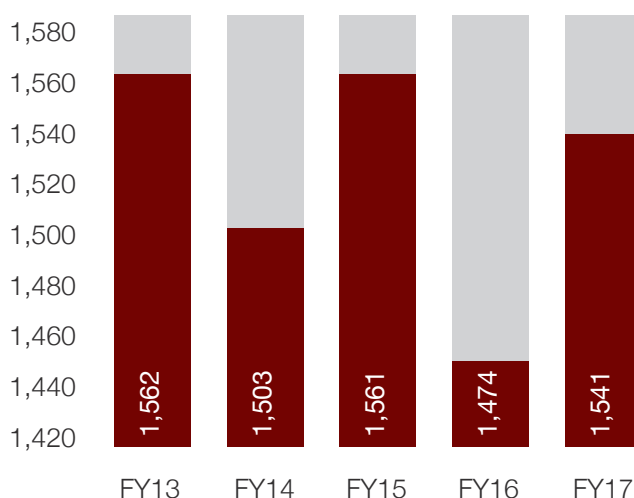


## Drug Distributor Summary:

All in-state drug companies that ship/transfer legend pharmaceuticals or drug-related devices are required to be licensed as a Missouri drug distributor. Additionally, out-of-state drug companies or manufacturers that ship/transfer legend drugs or drug-related devices into Missouri must hold a Missouri drug distributor license.

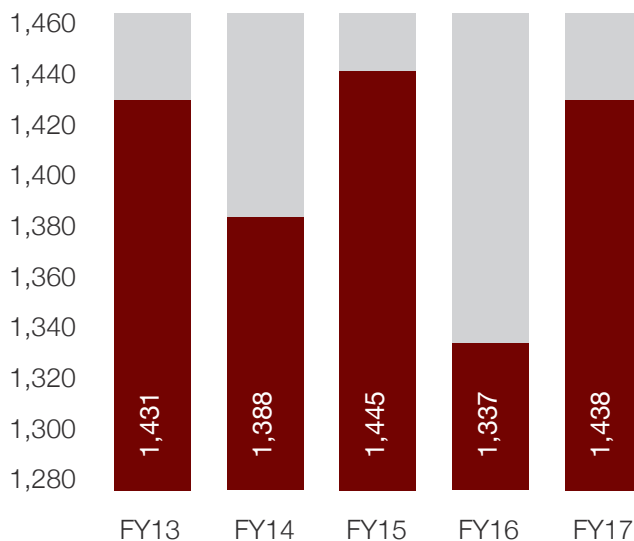
## TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FISCAL YEAR

The total number of licensed drug distributors and drug distributor registrants increased by 4.5% to 1,541 licensees/registrants (1,439 drug distributors and 102 drug distributor registrants). The Board historically experiences an increase in drug distributors/registrants after a drug distributor renewal year as with FY17.



## TOTAL DRUG DISTRIBUTORS BY FY

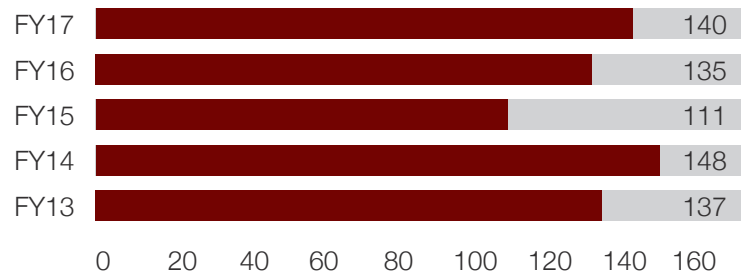
The number of licensed drug distributors increased 7.5% which is once again consistent with historical trends after a drug distributor renewal year.



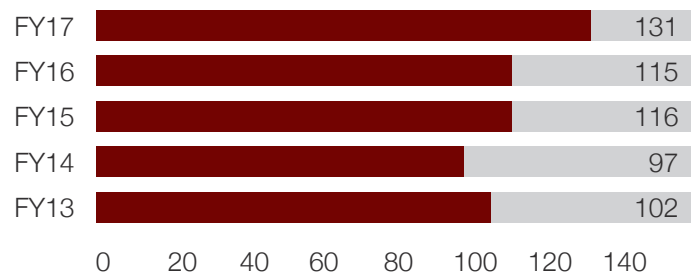


## NEW DRUG DISTRIBUTORS LICENSED

Newly licensed drug distributors remained consistent:

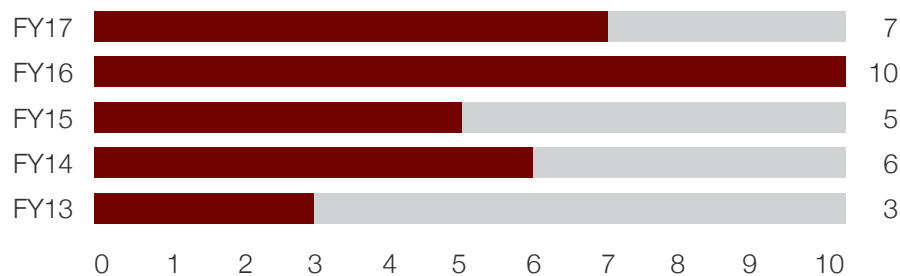


## TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY



## NEW DRUG DISTRIBUTOR REGISTRANTS

While historically lower, the number of drug distributor registrants decreased by 30% as reflected below:



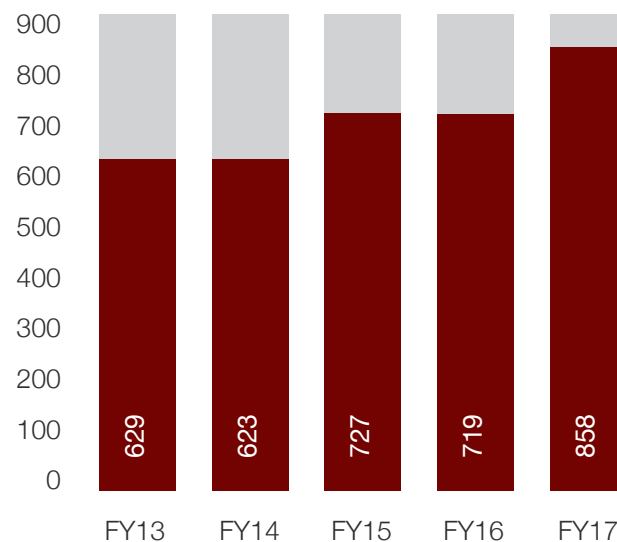
# Complaint Summary



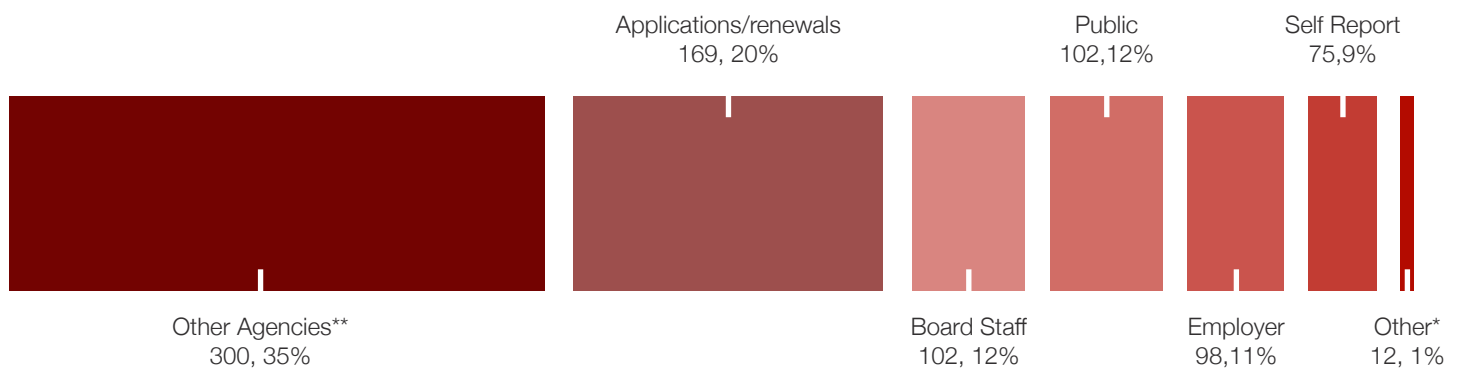
## Complaint Summary

All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 858 new complaints in FY 17 representing a 19% increase. Of the 858 complaints handled, 561 complaints were practice-related complaints (65%) while 297 complaints were non-practice related Missouri Department of Revenue tax compliance cases (approx. 35%).

## Complaints Handled by FY



## Complaints by Source



\* Includes complaints from licensees, auditors & insurance companies. Other agency complaints include Dept. of Revenue tax suspensions (298 cases)

# Complaint Summary



## FY17 COMPLAINTS BY CATEGORY

Adulterated Drugs	2
Alcohol Use/Suspected Alcohol Impairment	11
Audit Findings	5
Billing for Services Not Rendered	1
Compounding	5
Confidentiality	2
Criminal History	34
Disciplinary Action in Another State	74
Dishonesty	1
Dispensing Error	13
Diversion	5
Drugs	15
Employer Disciplinary Action (Non-Drug)	1
Expired Drugs in Inventory	7
Felony	1
Fraud (Unspecified)	1
Fraudulent Prescription	4
Drug Impairment (Suspected/Actual)	5
Drug Possession/Use	3
Improper Controls	66
Immunization/Administration	39
Improper Dispensing	28
Incompetence	3

Insurance Fraud	3
Licensure Applicant	158
Loss of Drugs	6
Malpractice	1
Mandatory Reporting Violation	1
Misbranding	2
Misconduct (Non-Drug Related)	1
No Jurisdiction/Other	8
Pharmacy Permit Violation	1
Previous Disciplinary Action	2
Repackaging/Prepackaging	1
Security	1
Substitution	3
Theft of Drugs	16
Theft of Money	13
Unauthorized Dispensing	2
Unlicensed Practice	37
Unprofessional Conduct	5
Unsanitary Pharmacy	1
Unsupervised Dispensing	4
Veterinary	1
Violation of Disciplinary Order	6

*\*Complaints by category will not equal the # of FY17 complaints due to multiple allegations in a single complaint.*

## HISTORICAL COMPARISONS

	Dispensing Errors	Improper Dispensing	Loss of Drugs	Pharmacy Permit Violations	Practicing w/o License	Diversion/Theft of Drugs
FY 17	13	28	6	1	37	22
FY 16	15	33	12	4	8	27
FY 15	47	34	6	21	35	30
FY 14	68	15	8	16	28	26
FY 13	52	27	4	20	48	35

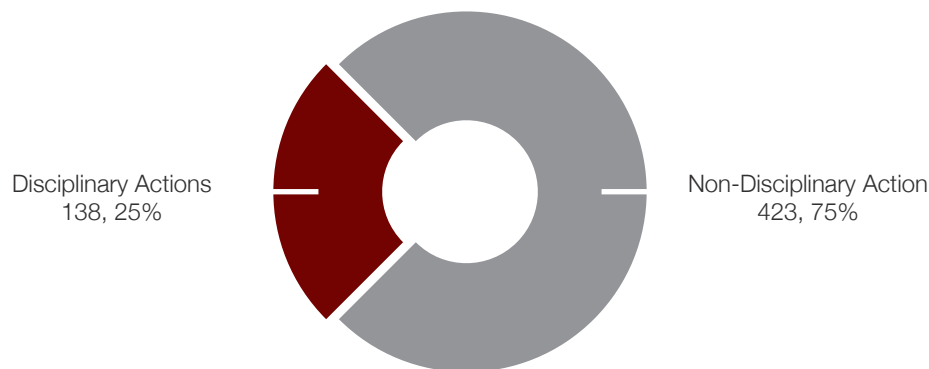
# Complaint Summary



## COMPLAINT DISPOSITIONS

The Board issued final dispositions on approximately 859 complaints/cases in FY17 which included 298 Department of Revenue tax suspension complaints and 561 non-tax related complaints.<sup>2</sup> Final complaint dispositions in FY17 increased by 24.67%, which included a 71% increase in Dept. of Revenue tax cases. Non-tax related cases increased by 12% from 515 cases in FY16 to 561 cases in FY17. The 561 non-tax related cases were disposed of as follows:

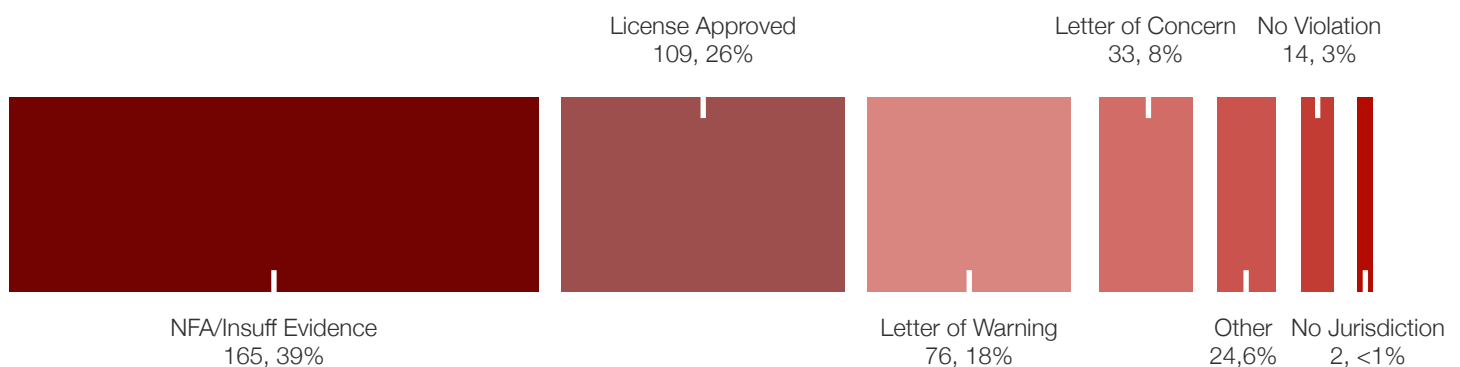
### (Non-Tax Related Complaint Dispositions)



The ratio of non-disciplinary actions to disciplinary actions remained consistent from FY16 when 26% of non-tax related complaints were closed with discipline and 74% were closed without disciplinary action. Although the ratio remained consistent, the number of FY17 disciplinary actions slightly increased by 2.9%.

## SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 423 non-tax related complaints closed without disciplinary action in FY17: (see Disciplinary Action section for complaints closed with disciplinary action)



\* Other: Closed [14], Closed But Flagged for Future Review [8], Cease & Desist [1], Denied [1]

<sup>2</sup> The 859 complaint dispositions includes complaints received in prior fiscal years but finally determined in FY17. As a result, the number of complaints disposed of in FY17 will not equal the number of new complaints received.

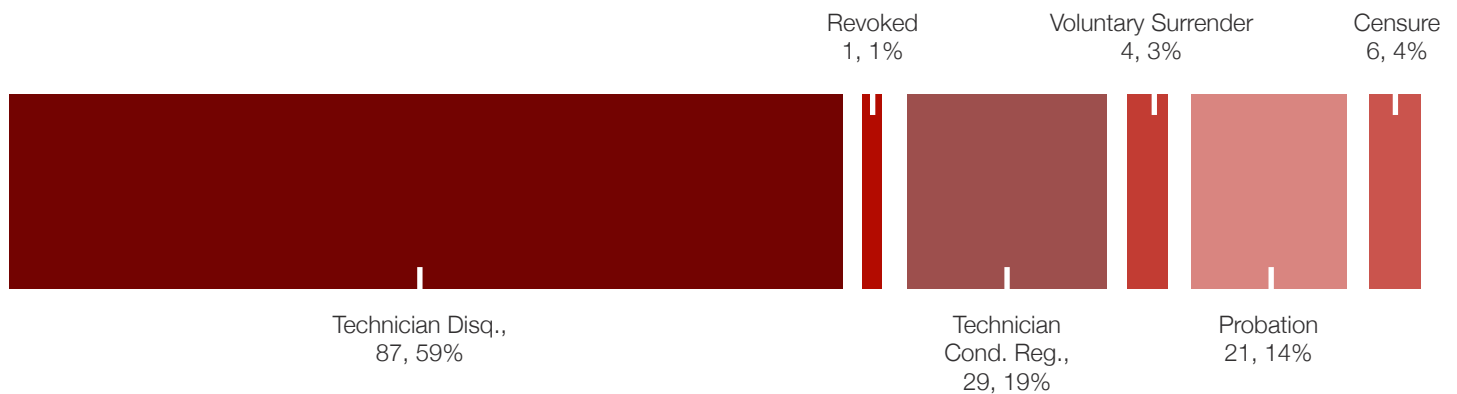
# Disciplinary Actions



## Summary of Disciplinary Action

The Board issued disciplinary action in 446 cases in FY17, representing a 43.8% increase from FY16. One-hundred and forty-eight (148) practice related disciplinary actions were issued (33%) while the remaining 298 cases involved non-practice related Department of Revenue tax suspensions (67%). The increase in disciplinary actions is attributed to an additional 146 non-practice related tax suspensions in FY17.

The following disciplinary action was taken in the 148 practice-related disciplinary actions issued:



## DISCIPLINARY ACTIONS BY CATEGORY

Technician Registrations Suspended under § 324.010 (tax purposes)	298
Technicians Disqualified	87
Technicians Placed on Conditional Employment	29
Intern Pharmacist Probated	1
Pharmacist Licenses Censured	6
Pharmacist Licenses Probated	13
Pharmacist Licenses Revoked	1
Pharmacist Licenses Voluntarily Surrender (Treated As Discipline)	4
Pharmacy Permits Probated	7
<b>TOTAL</b>	<b>446</b>

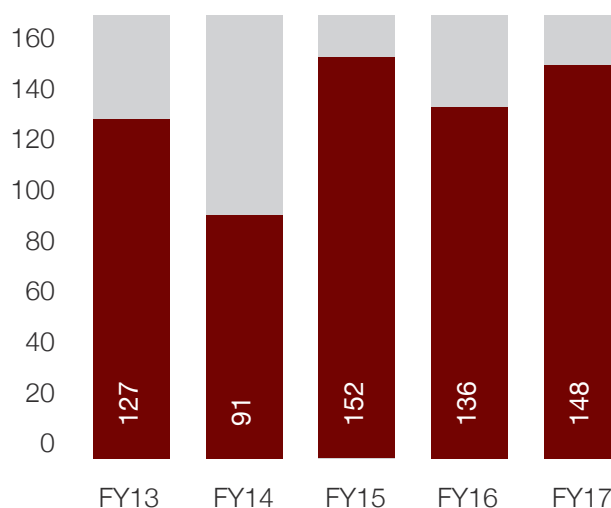
# Disciplinary Actions



## PRACTICE RELATED DISCIPLINARY ACTIONS \*

One hundred and sixteen (116) pharmacy technicians, 24 pharmacists, 1 intern pharmacist, and 7 pharmacies were disciplined for practice-related issues during FY17. No drug distributors were discipline in FY17. Total practice related disciplinary actions increased by 8.9% from FY16 as reflected below:

### (Total Practice-Related Disciplinary Actions by FY)

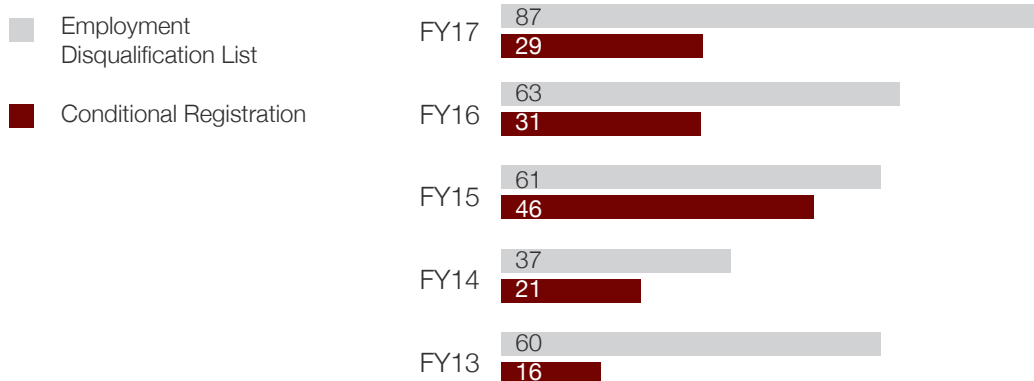


\* Does not include tax suspensions pursuant to § 324.010, RSMo.

## PHARMACY TECHNICIAN DISCIPLINE

Approximately 78.37% of practice related disciplinary actions in FY17 involved pharmacy technicians placed on the Employment Disqualification List or issued a conditional registration pursuant to § 338.013, RSMo. While the number of technicians issued a conditional registration remained consistent, technicians placed on the Employment Disqualification List increased by 38% as reflected below:

### (Practice Related Pharmacy Technician Discipline by FY)





# Disciplinary Actions



## GROUNDINGS FOR TECHNICIAN EMPLOYMENT DISQUALIFICATION

(Cause for EDL / # Disciplined)

- Alcohol Use/Prior Impairment (2)
- Criminal History (23)
- Diversion (20)
- Misconduct/Unauthorized Dispensing (2)
- Illegal Drug Usage/Positive Drug Test (23)
- Theft (Non-Drug Related) (9)
- Unlicensed activity (Working while suspended/expired) (1)

## GROUNDINGS FOR TECHNICIAN CONDITIONAL REGISTRATION

(Cause for CR/ # Disciplined)

- Criminal History (19)
- Discipline by Another Agency (1)
- Prior Disciplinary Action (1)
- Improper/Prior admitted drug use (2)
- Improper/Unauthorized Dispensing (2)
- Theft (Non-Drug Related) (1)
- Unlicensed activity (Working while suspended/expired) (3)

## PHARMACIST DISCIPLINE BY FY:

Pharmacist discipline decreased by 11% with 24 pharmacists disciplined for practice-related issues as reflected below:

	FY13	FY14	FY15	FY16	FY17
Censure	11	7	5	6	6
Probation	10	6	5	14	13
Suspension	0	0	2	0	0
Suspension/Probation	5	2	4	4	0
Revocation	2	2	1	3	1
Voluntary Surrender (treated as discipline)	—	—	—	—	4
<b>TOTAL</b>	<b>28</b>	<b>17</b>	<b>17</b>	<b>27</b>	<b>24</b>

# Disciplinary Actions



## PHARMACY DISCIPLINE BY FY

Pharmacy discipline declined 50% as follows:

	FY13	FY14	FY15	FY16	FY17
Censure	4	2	9	4	0
Probation	9	9	12	8	7
Revocation	1	0	0	2	0
Voluntary Surrender	2	0	0	0	0
<b>TOTAL</b>	<b>16</b>	<b>11</b>	<b>21</b>	<b>14</b>	<b>7</b>

## DRUG DISTRIBUTOR DISCIPLINE BY FY

	FY13	FY14	FY15	FY16	FY17
Censure	0	0	0	0	0
Probation	4	0	3	1	0
Voluntary Surrender	0	0	0	0	0
<b>TOTAL</b>	<b>4</b>	<b>0</b>	<b>3</b>	<b>1</b>	<b>0</b>

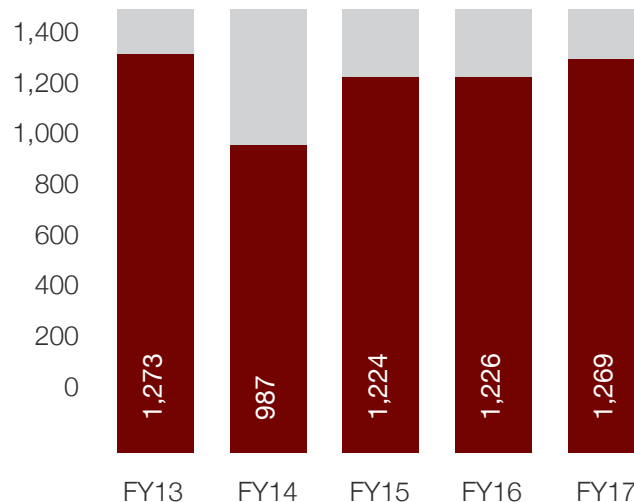


## Inspection/Investigation Summary

The Board conducts new and routine inspections of all Missouri located pharmacies and drug distributors. Board inspectors also conduct investigations as assigned.

- Board regulatory inspections remained consistent with a total of 1,269 inspections conducted in FY17 (1,071 pharmacy inspections/198 drug distributor inspections). Forty-two (42) drug distributors were exempt from inspection pursuant to 20 CSR 2220-5.040 as authorized for facilities inspected by the U.S. Food and Drug Administration.
- The Board continues to inspect all sterile compounding pharmacies annually.
- A total of 247 investigations were completed in FY17 by Board staff/inspectors, representing a 17% increase from FY16.

## Pharmacy/Drug Distributor Inspection Summary



## INSPECTION FINDINGS

At the conclusion of an inspection, the inspector may initiate one of the following resolutions:

- **Observation Report:** Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- **Compliance Notice:** Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- **Quality Assurance Report:** Issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug.
- **Investigation:** An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.



## FY17 INSPECTION RESULTS\*

Approximately 70% of Board inspections resulted in violations noted or a compliance notice being issued, representing a 5% decrease from FY16. FY17 inspection results are summarized below:



Compliance notices issued after inspection decreased by 33.45%; No violation findings increased by 22%. Violations noted remained consistent.

*\* Includes inspection results for follow-up inspections and investigations.*

# Compounded Drug Testing



## Testing Summary

In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2017:

Dosage Form	Tests Performed
Capsule	17
I.V. solution	26
Injection	12
Oral suspension	3
Sublingual Tablet	3
Suppository	1
Cream/ointment	9
Troche	6
Vaginal Gel	1
Vaginal Suppository	2

Test Results	Tests Performed	Percentage
Satisfactory	52	72.5%
Unsatisfactory	22	27.5%
Total	80	100%

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from 66% to 235.2%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

Drugs With Unsatisfactory Results	
Alprostadi/Papaverine/Phentolamine Injection	Nifedipine/Lidocaine Cream
Biest/Progesterone Capsule	Ondansetron I.V. Solution
Biest/Progesterone/Testosterone Cream	Piperacillin/Taxobactam I.V. Solution
Cefazolin Injection	Piroxicam Capsule
Cefepime Injection	Progesterone Capsule
Estradiol Troche	Sildenafil Sublingual Tablet
Estradiol Valerate/Progesterone Vaginal Suppository	Tiestrogen/Progesterone Troche
Estradiol/DHEA/Pregnenolone/Progesterone Cream	Vancomycin I.V. Solution
Naltrexone Capsule	



## Rule Changes

The Board continued to review Missouri's pharmacy rules to ensure appropriate and consistent regulation. The following rules were pending, approved and/or promulgated in FY17:

## Promulgated Rules

PROMULGATED RULES		
20 CSR 2220-2.095	Collection of Medication for Destruction	Rule revised to allow pharmacies to collect medication for destruction purposes
20 CSR 2220-2.200	Sterile Pharmaceuticals	Substantially revised Missouri's sterile compounding requirements and enhances patient safety standards

APPROVED RULES (Rules approved by the Board/Pending approval for filing)		
20 CSR 2220-2.650	Standards of Operation for a Class J: Shared Services Pharmacy	Updates Missouri's Class-J pharmacy requirements and creates exemptions to additional licensure for pharmacies dispensing medication to another pharmacy for administration by a licensed healthcare professional

# Strategic Planning Initiatives



## Strategic Planning Initiatives

As part of its regulatory mission, the Board holds an annual strategic planning meeting to assess Board operations and review Missouri's regulation of pharmacy practice. The Board's FY17 strategic planning meeting was held on July 19, 2016. As part of strategic planning, the Board voted to pursue the following initiatives:

### LEGISLATIVE PROPOSALS

The following legislative proposals were approved by the Board for the 2016-2017 legislative session:\*\*

- Charitable Pharmacies: Would establish a licensure classification for charitable pharmacies and allow the Board to promulgate separate rules for charitable pharmacy operations.
- Implementation of the Drug Quality and Security Act: Would establish licensing requirements for third-party logistic providers as defined by the federal Drug Quality and Security Act.
- Continuing Education: Would amend § 338.060, RSMo, to clarify that pharmacists are required to obtain thirty (30) hours of continuing education every biennial renewal period.
- Rx Cares for Missouri: Would allow the Board to establish and allocate funds for the Rx Cares for Missouri Program to promote medication safety and prevent prescription drug abuse, misuse and diversion.
- Civil Penalties: Would grant the Board authority to issue civil penalties.
- Prescription Format: Would amend § 338.056, RSMo, to eliminate Missouri's mandatory two-line prescription requirement.

\*\* Legislative proposals must be approved by the Governor prior to submission.

### RULE REVIEW

The Board adopted a 2020 Rule Review initiative to review and update Board regulations. As part of the initiative, all rules will be reviewed by the Board prior to 2020 with the goal of:

1. Eliminating duplicate or unnecessary regulation;
2. Ensuring rule appropriateness and consistency; and
3. Updating and modernizing rule language.

Rule review meetings will be open to the public; Public participants may submit oral, written or electronic comments. A public rule review schedule was posted on the Board's website.

### COMPLIANCE

The Board continued its campaign to encourage and promote patient safety and safe pharmacy practices. In addition to the Board's compliance webinars, the Board sponsored/hosted the following in FY17:

- 2017 Missouri Pharmacy Diversion Conference: Two pharmacy diversion conferences were hosted by the Board in FY17 to educate licensees on ways to detect and prevent pharmacy robbery and drug diversion. The free continuing education programs were hosted in St. Louis (July 16, 2017) and Kansas City (May 5, 2017) and featured both state and national leaders in addressing drug diversion. Program presenters included representatives from the United States Attorney's Office, the United States Drug Enforcement Administration, the Missouri Bureau of Narcotics and Dangerous Drugs and Board staff.